DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

CHARTER

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

PURPOSE

The Director, National Institute of Environmental Health Sciences (NIEHS), establishes the Scientific Advisory Committee on Alternative Toxicological Methods (the Committee) to fulfil section 3(d) of Public Law 106-545, the ICCVAM Authorization Act of 2000 [42 U.S.C 285l-3(d)]. The purpose of the Committee is to advise the NIEHS, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NTP Center) regarding ICCVAM activities. The Committee also advises the NIEHS and the NTP Center on the NTP Center's activities. Outside advice by an officially chartered committee becomes key to the acceptance and the level of trust by the scientific and public sectors and to the broadening of partnerships beyond government.

The Department of Health and Human Services (Department) has a vital role in safeguarding public health and developing strategies to accurately determine the safety or adverse health effects of chemicals and other substances to which the public are exposed. The Secretary of Health and Human Services established the NTP on November 15, 1978, to strengthen the Department's activities in the testing of chemicals of public health concern as well as in the development and validation of new and better-integrated test methods. The NTP is headquartered at the NIEHS and the NIEHS Director serves as Director of the NTP. Pursuant to section 463A of the Public Health Service Act, as amended (Act), 42 U.S.C. 285l-1, the NIEHS and the NTP established the ICCVAM in 1998 and the NTP Center in 1998. Section 3(a) of the ICCVAM Authorization Act of 2000 [42 U.S.C. 285l-3(a)] designates the ICCVAM as a permanent interagency coordinating committee of the NIEHS under the NTP Center.

The purposes of the ICCVAM as defined in the law are to increase the efficiency and effectiveness of Federal agency test method review; eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies; optimize utilization of scientific expertise outside the Federal government; ensure that new and revised test methods are validated to meet the needs of Federal agencies; and reduce, refine, or replace the use of animals in testing, where feasible.

The NTP Center supports activities and collaborates with the ICCVAM to facilitate the development, scientific review, validation, and interagency consideration of novel toxicological methods of multiagency interest that predict human health risks while reducing, refining, and/or replacing animal tests. The NTP Center promotes participation and communication with stakeholders throughout the process of test method development and validation.

AUTHORITY

Section 3(d) of Public Law 106-545 [42 U.S.C. 285l-3(d)]. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Committee provides advice to the Director of the NIEHS, the ICCVAM, and the NTP Center regarding the following statutorily mandated ICCVAM functions:

(1) Review and evaluate new or revised or alternative test methods, including batteries of tests and test screens, that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest;
(2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods;
(3) Facilitate and provide guidance on the development of validation criteria, validation studies, and processes for new or revised or alternative test methods and help facilitate the acceptance of these scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders;
(4) Submit ICCVAM test recommendations for the test methods reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (Secretary) (or designee), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for a test methods, including batteries of tests and test screens, for chemicals or class of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods;
(5) Consider for review and evaluation, petitions received from the public that-- (A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and (B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method;
(6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the response from the agencies regarding these recommendations; and
(7) Prepare reports to be made available to the public on its progress under the Act.

The Committee also provides advice to the Director of the NIEHS and the NTP Center on activities and directives relating to the NTP Center in three areas:

(1) Priorities and opportunities for alternative test methods that may provide improved prediction of adverse health effects compared to currently used methods or advantages in terms of reduced expense and time, reduced animal pain and distress, and the reduction, replacement, or refinement of animal use;

(2) The adequacy and effectiveness of processes used for determining the scientific validity and acceptability of proposed new or revised or alternative test methods; and
(3) Ways to foster more effective and productive interactions between Federal agencies and other involved stakeholders, including test method developers.

As necessary, the Committee and its subcommittees may call upon special consultants; assemble ad hoc working groups; and convene conferences, workshops, or other activities.

STRUCTURE

The Committee shall consist of 15 members, including the Chair. Voting members shall be appointed by the Director, NIEHS, and include representatives from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories. Knowledgeable representatives from public health, environmental communities, or organizations using new or alternative test methodologies may be included as appropriate. There shall be at least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of the following categories: (1) personal care, pharmaceutical, industrial chemicals, or agricultural industry; (2) any other industry that is regulated by one of the Federal agencies on the ICCVAM; and (3) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986, as amended.

The Director, NIEHS, shall select the Chair from among the appointed members of the Committee. A quorum for the conduct of business by the full Committee shall consist of a majority of currently appointed members.

Members shall be invited to serve for overlapping terms of up to four years; terms of more than two years are contingent upon renewal of the Committee by appropriate action before its expiration. Members may serve after the expiration of their terms until a successor has been appointed.

The membership of the Committee shall include, as nonvoting ex officio members, the agency heads or their designees from the Federal agencies represented on the ICCVAM. International regulatory and/or international research organizations may also be invited to designate a liaison member to the Committee. Liaison members shall not have voting privileges.

As necessary, standing and ad hoc subcommittees, composed of members of the parent committee, may be established to perform specific functions within the Committee's jurisdiction. The Department Committee Management Officer shall be notified upon the establishment of each standing subcommittee and shall be given information on its name, membership, function, and estimated frequency of meetings.

Upon approval by the Chair, the advice of a subcommittee shall be considered the advice of the full Committee. All subcommittees shall report to the parent committee. A quorum of each subcommittee shall include three voting members of the parent committee.
A member of one subcommittee may serve as a voting member of other subcommittees when that member's expertise is required. However, that member shall not be counted in determining the presence of a quorum.

Management and support services shall be provided by the Office of the Director of the Environmental Toxicology Program, NIEHS and the NTP Center.

MEETINGS

Meetings of the full Committee shall be held approximately two to three times a year at the call of the Chair with the advance approval of a Government official, who shall also approve the agenda. A Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept as required by applicable law and Departmental policies.

COMPENSATION

Members shall be paid at the rate of $200 per day, plus per diem and travel expenses, as authorized by section 5703, Title 5 U.S.C., as amended, for persons in the Government service employed intermittently. Members who are officers or employees of the United States Government shall not receive compensation for service on the Committee.

ANNUAL COST ESTIMATE

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support is $45,940. The estimate of annual person-years of support is 0.8, at an estimated annual cost of $64,257.

REPORTS

In the event a portion of a meeting is closed to the public, a report shall be prepared which shall contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates, and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the Scientific Advisory Committee on Alternative Toxicological Methods shall expire on December 18, 2005.

APPROVED:

Nov 17, 2003
Date

Kenneth Olden
Director, NIEHS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

NOTICE OF RECHARTER

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

This Committee was established by statute and has functions which are of a continuing nature so that its duration is not governed by section 14(a) of the Federal Advisory Committee Act but is otherwise provided for by law. The Committee is hereby rechartered in accordance with section 14(b)(2) of that Act.

Nov 17, 2003
Date

Kenneth Olden
Director, NIEHS